Welcome and thank you for standing by. At this time all participants will remain in a listen-only mode until the Q&A portion held at the end of the conference. If you'd like to ask a question at that time you may press star, then 1. This conference is now being recorded. If you have any objections you may disconnect at this time.

I would now like to turn the conference over to Jim Crockett. Thank you, you may begin.

So good morning to those down in the Caribbean and - well, good afternoon. Good morning for those out in the Pacific. And thanks for joining us.

Again, welcome to this Sustaining Zika Response in 2017: A Laboratory Specific Webinar. Again, this is our two-way discussion, a little deeper dive than what we had on our call the first of March.

Understand this is more laboratory focused for this webinar. We have invited participants from across various state health entities. So they'll be joining us on the call and so we'll go from there.

We had this call earlier. About three hours ago, we did the same type of thing. This is way more focused on the island and territories concerns, so we're expecting a smaller audience this afternoon. That should allow us for a more detailed discussion, if you want.
So really the purpose today is for a quick 20-minute session or less or thereabouts for a kind of slide presentation. Then we want to open up really to what your questions, concerns or gaps are, so we can help address for your specific area.

So following today's conversation, we'll show, as a final slide, you have seven more webinars of this type occurring. The next two of significance, just so you're aware, deal with risk communications and joint information center operations. That's next week on the 22nd of March, for the Eastern seaboard date.

And we have an Epi Task Force/Surveillance update. That's on March 23rd for the East Coast, US time for a date.

For those out in the Pacific, we anticipate, because of the times, we would capture those on a link. Both the complete conversation and the slides, have those posted to a website to get access at a later date. Presentation times, we'll just match up with those islands further east of American Samoa and Guam. So we'll work those out for you.

And, keep in mind, we are updating our partner guidance - excuse me - our Zika Response guidance as we learn more. So, of that you will hear today. And we would ask, if you have any questions we don't answer here today, as usual, please send them to us at Preparedness@CDC.gov. That's Preparedness@CDC.gov. We'll be sure to address those at a later time.

So today's presentations for the laboratory task force, I'd like to introduce Dr. Eddie Ades, who is with us with our laboratory task force. Sir, I turn it over to you for any other introductions to you and your team.
Eddie Ades: Okay, thank you very much. I appreciate that. Good afternoon to some and good morning to others. I'm ready for my dinner, so we'll make this short and sweet. No, I'm only kidding. I have plenty of time to take any and all questions, so hopefully this will stimulate some and we can talk through some of that.

Joining me this afternoon will be Dr. Robert Lanciotti, who is a subject matter expert in Zika. He joins us from Fort Collins as part of this emergency response effort.

And some of you have seen several of his papers regarding this particular arbovirus. So Rob is on the phone as well and will be available for questions and answers at the end of my brief conversation about some of the slides that we've provided.

Jim Crocket: Eddie, if I can a quick administrative note. Kosrae from out in the Pacific is still trying to connect with us. They may come in a little late, so we may have kind of back up with them.

Eddie Ades: Okay.

Jim Crockett: Thank, you sir. Sorry about the interruption.

Eddie Ades: No problem. So if we could just jump onto Slide 5 which is why this is currently important. Well in the continental or CONUS, we expect that we'll continue to have travelers coming back to the U.S. from areas that have active disease or endemic disease at this moment.
So we do expect to see additional cases here in the US and also we would expect in the areas that you're in currently. We're also expecting to see a continuation of disease activity.

We also expect local transmission on the islands. And the big key is the fact that, as many of you on the phone are aware, the big issue is obviously cross reactivity and diagnostic test performance and the fact that the serology is limited because of this cross reactivity. And some of you are aware of, or have already asked for the ability to no longer continue to do one - the confirmatory PRNT Testing for serology.

So we'll talk a little bit about that. And I can address some of the issues around that. So that you understand, if you do want to try to not continue to do PRNT the FDA does require a few things that you must provide.

And we can help you with the guidelines and guide you through that, so that we could make the application for you. And we can talk a little bit about that in a minute.

So, you know, clearly, we feel that we've had some successes. There's still a lot to be done. We got the MAC-ELISA test out last February, and we got the Trioplex out in March.

So we were able to have EUAs - Emergency Use Authorizations - administered so that we were able to do some testing quickly and to continue to help understand the issues surrounding this particular arbovirus disease.

We continue to manufacture and we do continue to distribute the MAC-ELISA and the Trioplex. We also are continuing to distribute reagents for the
assays domestically and internationally. And we are providing confirmatory testing and surge capacity, as most of you are aware.

We are prepared for surge capacity coming up this coming season. And we can talk a little about that, but we have laboratories capable of doing all of the assays at Fort Collins, here in Atlanta, and also at Puerto Rico. So in all three areas we have ability to run the Trioplex or RT-PCR; we have the ability to do MAC-ELISA or serology, and we also have ability to do PRNT.

So we are here to help and provide access and need to additional testing facilities if required. With regard to concerns, I mean, I think that everybody on the phone would agree that the greatest concern, although it's listed secondly, is the specificity of the diagnostic assay.

Clearly, we are aware that there are some issues. We are also aware that the FDA issued a bulletin regarding commercial lab utilization of InBios and some issues associated with it. That alert has not been withdrawn yet.

We are working closely - our SMEs out at Fort Collins, are working closely with the InBios people and the LabCorp people to try and get some of those issues resolved so that we can clearly let commercial labs switch over to - away from the MAC-ELISA and utilization of the InBios.

The other assays that we’ve looked at internally were both the NovaTec and EUROIMMUN. And as you can see, they all have different sensitivities and specificities. One of the issues that I would say is that - as we talk about testing algorithms and I discuss two different issues - about the first concern, about the testing algorithms.
The first, the issue about testing algorithms are that, you know, right now our confirmatory test is PRNT. We're hoping that perhaps with a new or different serology test, we may be able to exclude PRNT and use, as a secondary or confirmatory test, a different serology test that might pick up a different epitope or antigenetic portion of the virus from the one that MAC-ELISA recognizes.

So that's part of our ongoing discussion about new diagnostics. And we're working hard to take a look at that.

We're also working hard to look at the viral persistence issue. Most of you are aware that in the algorithm as it currently exists. The NAT testing is recommended for zero to 14 days and then switch over to serology.

Here we're looking at, with viral persistence, the potential to broaden the window from zero to 14 days maybe out to zero to 28 days with the hopes that we would pick up a few more patients who could be diagnosed by RT-PCR and then would not have to go through serology testing.

We've had the ability to get data from a few laboratories that have already started to do this, to some degree, just to see what it would look like. And where we had hoped that there would be a larger percentage of individuals that we would detect who were RT-PCR positive 14 to 28 days in that part of the window, we actually find that the number is approximately 1 to 2% of the population that we've tested so far.

So the numbers don't indicate per se a huge turnaround in the number of individuals that are going to be excluded from doing serology because they fall into RT-PCR positive for Zika. So we're now analyzing the situation, and asking the question, whether opening the window and letting the laboratories
have the discretion to do that or not is something that we've had a lot of discussion about.

And we feel that probably giving people a little more leeway in terms of their ability to do expanded testing might reduce the number of serologic-tested people. So we're having discussion about that at the current time.

We're also concerned, as others are, about the results and the turnaround time from sample receipt to when the results reach a physician. Clearly, we know that when we get a sample in, our turnaround time is somewhere between 7 to 10 days.

We've heard stories about three, four, five weeks' turnaround, so on and so forth. And one must also - and this isn't an excuse on our part or anybody's part, but some of that issue is that we're waiting for the sample, so there's a time in there. And there's a time on the back end where we send the results back out and then there's a lag time there as well.

So some of that window of responsibility with regard to getting the information is not necessarily within our own control. And we're trying very hard to make sure within our own control that we're doing our turnaround time as quickly as possible. And we're somewhere between seven and ten days at this particular time.

I would say that we're also trying to figure out who we can get HL7, which is the Health Level 7 messaging, set up so that we can get it to all the public health labs and to some of the island labs as well. So that's part of what we're working on right now.
We've gotten some funding to be able to do that. We just got that funding, so we're just starting to work on that as well, as I speak right now.

So moving on to the next slide, we have several priorities going forward. We continue to talk with our SMEs at Fort Collins and reference lab support regarding surge, regarding utilization of our labs to help facilitate any testing by any of the groups, anywhere. And, you know, so we can either have samples sent to Fort Collins and/or to Atlanta.

With regard to - we are maintaining all our surge labs through this particular coming season - we hope it's a mild season and we don't need to utilize them, and we'll be able to do other diagnostic evaluation while we're in surge mode if need be.

We are always here to assist the state and territorial labs as needed. We're doing a lot of performance diagnostic assay assessments right now, looking at urine, blood, and other body fluids. We're also adding stabilizers now to urine to look to see if that's going to help with our evaluation and testing and sensitivity. So those are ongoing issues that we're looking at the moment.

We’re also looking at, as I said earlier, the window of the algorithm. So that would increase some of our flexibility, your flexibility to decide, you know. What is a good window to test the individuals that are being sent to you and make some decisions about whether that extra 14 days in testing on the NAT side would make a difference to your laboratories. So we're trying to work with that algorithm at the current time.

And of course, as I said, we're conducting lots of new and different diagnostic research as I talked about. We do plan to continue to work with our
commercial laboratory partners to get them as much information as possible. We do get samples from them.

We do evaluate, we do confirm. We do work and talk with them all the time. So we are continuing to look at ways with them to speed up the process as well.

So there are currently - there are currently 12 PCR assays, including the Trioplex, for the FDA. And there are currently two IgM assays that are currently FDA/EUA approved, one of them being the MAC-ELISA, the other being the InBios, as I mentioned earlier, where there have been a few issues. But we believe we're getting those issues resolved and will let people know shortly that, you know. We feel that it's now at a point where it's comfortable to have the commercial labs switch back to InBios from MAC-ELISA.

With regard to, again, new research regarding molecular and serologic diagnostic tools, just a few things that we're currently looking at and doing are looking at increasing sensitivity through high throughput of specimen volume and type. We're looking at reducing volumes. We’re looking at changing the enzymes.

We're looking at changing the buffers in order to reduce the amount of sample yet increase the amount of virus that we can detect in that sample by changing enzymes and changing buffers. So that's ongoing studies, that's with serum, whole blood, urine. As I said, we're doing urine stabilizer studies at the moment as well.

We also have people working on looking at not only IgGM but IgG assays using multiplex bead assays. That's ongoing studies. We also have MALDI-
TOF studies looking at IgGM as a diagnostic test - too early to say anything about those, at this point.

But they are studies that we're starting to evaluate. We're also looking at some of our recombinant antigens and other ways to express antigens for some of the platforms and tests that were currently working on.

With regard to Puerto Rico, I think that most people that are on the phone from there and the other islands are aware that Puerto Rico had a really hard season last year. They basically had about 38,000 confirmed cases. Their peak was during September and they literally were talking about 500 positive cases per week at one point.

So, it was a long, hard summer for them. We certainly hope that this summer will be less strenuous with regards to Zika-associated issues. We also expect that, since the majority of the testing and the detection was late fall, this coming summer we're expecting to see about Zika-associated birth defects.

A lot of EPI studies, a lot of surveillance studies, and a lot of blood work is being planned to be done to follow those children as they're brought into the world.

With regard to the new season, we expect it somewhere to start in May in Puerto Rico and we are hoping that it will be less intense. But we are prepared for a strong season again and we have surge in place. And we are also suspecting that we could have dengue and/or chikungunya at the same time, so we're preparing ourselves for that as well.

With regard to other big issues in Puerto Rico, I think the two things that are relative are that, one, they are no longer doing PRNT testing, and, two, they
have made a decision at the Puerto Rico Department of Health that they are
doing all of their samples first by NAT testing or RT-PCR. So they're doing
everything that comes in the door for NAT testing first.

And we're looking at that as part of a change in overall algorithm as well.
That's an ongoing conversation. We will have that information in the next
couple of weeks as well as we look into whether that's a value added to the
algorithm. And we'll have more information about that going forward.

So I think that I'm going to stop there and open the floor up for conversation
and questions, and both Rob - Dr. Lanciotti and I are available for your
questions. So with that, let me know what we can do to help.

Jim Crockett: Karen, can we open it up to see if there are any questions out there or any
discussions we wish to have? I know you've got a smaller group on the call
earlier today but really more time for questions that way.

Coordinator: Thank you. At this time if you'd like to ask any questions, please press star,
then 1 and record your first and last name clearly when prompted. Again, if
you have any questions please press star, then 1 at this time.

One moment please. Hi, the first question is coming from (Amy). Ma'am,
you're line is open.

(Amy): Hello, everyone. Thank you so much for the presentation, Dr. Ades, I really
appreciate it and thank you to all the CDC staff for making these updates and
time available for the Pacific. It's a little bit easier not having to wake up at 4
o'clock in the morning for some, so appreciate that.
I do have a couple of - I think these are more comments rather than questions. And it goes back to sort of the issue here, sustainable response, to not just Zika but any sort of arboviral, you know, outbreaks in the Pacific. And given our climate, similar to that of Puerto Rico, for us it's not some much even obvious as sort of a constant issue that we have to deal with.

I'm not a lab person, so I'm not going to speak to the specifics of the lab testing. But I just wanted to sort of lay a couple of points for the issue of sustainable surge response and other responses moving forward for Zika, and - you know - the continuing sort of tyranny of what I call geography demography available to constructive qualified human resources - you know - for our responses in the Pacific.

And, you know, when we have populations that are, you know, as small as 9,000 people in Kosrae for example, up to maybe maximum 159,000 in Guam, you know, we don't have the volume load that would rationalize sort of expanded capabilities for individual state and national level labs.

We have a situation of very infrequent air and sea travel, you know, some places we can only get to twice a week at most. So when we're talking about sending samples out for confirmatory testing to - let's say Fort Collins - I mean the turnaround time is on average, you know, two weeks or more. In some cases even far more than that.

So when we're talking about sort of a, you know, sort of a timely public health response, a lot of that is impacted by not really having the information in up-to-date at hand to be able to really insure that the response is appropriate, effective, and timely. So that's one issue.
For us in the Pacific, we really only have the one lab that we rely on, aside from Fort Collins, and that is the Hawaii State Public Health Lab. Now they have been a tremendous, tremendous support. So really kudos and hats off to, you know Ginnyi Pressler and the Hawaii Department of Health folks, who've really done their value service for the rest of the Pacific brothers and sisters and, you know, absorbing a lot of the costs on their own.

But in the situation where we have multiple sites across the Pacific that are experiencing you know, not just Zika, but it's the dengue and CHIK, and even some other communicable disease also, particular TB and Hansen’s disease. You know, we're seeing a sort of high volume load just from these small islands, just with these very specific areas of testing that all get to the Hawaii State Lab.

So, aside from Fort Collins, you know, the only other labs that we can send our samples to are Louis Pasteur Institute in New Caledonia, down South in the Pacific, near Australia. Then, the other one is the National Reference Laboratory in Sydney, Australia. And both of those are three-weeks plus, you know, turnaround time.

So, I think really one of the issues here of sort of sustainable response for any sort of arboviral or other communicable disease, other outbreaks in the Pacific, really, the issue of an alternate force for referral confirmatory testing for all the Pacific islands, I think, is a really critical question for us to really delve deep into.

And just to give some examples of what we're trying to do to make this work is, you know, the Pacific Island Health Officers' Association maintain a lab revolving fund. We have accounts with major airlines, the shippers, and labs in the Pacific Rim and across the region.
So we pay a lot of the shipping of these samples upfront on behalf of the USA PI health departments because a lot of these shippers and airlines will no longer honor purchase orders from government agencies in the Pacific because of major arrears.

And this speaks to sort of other systemic issues around administrative management ability to manage their funds in a way that maintains good vendor relations with the various sort of, you know, referral laboratories, airlines, et cetera, to ship those samples. So unfortunately, because that's been a major dysfunction in the Pacific, PIHOA stood in to do that.

The other issue is cost. So, for now what we're seeing, you know, for Zika samples from American Samoa to Hawaii on a twice a week flight is at one pop is $300 per shipment. And this is just one way. That's just from American Samoa to just to the airport and there's another fee that's, you know, about a hundred-some dollars from the airport to Hawaii State Public Health Lab with another courier service.

So, you know, at any given pop, we're looking at one set of samples just, you know, $300 to $500 just in one roll. So I think when we're looking at, you know, implementing some of the CDC guidelines, you know, the cost factor is an enormous issue for us in the Pacific.

Last but not least, I think one of the other issues is going back to sort of the issue of the regional lab. You know, we have to impose on multiple occasions from CDC to see how we can support Guam, for example, with a potential regional public health reference laboratory.
But also, even now, Guam has a new mosquito lab that they're just in the process of really sort of making that work well to be able to also do mosquito surveillance, you know, for the region.

Currently, you know, mosquito samples have to sent out to Kasama in Japan. So that's really the only alternative that we have at the moment for that type of surveillance. And, you know, at the same time, Guam Public Health has been validated for Trioplex. But that has not been available for the region at all for us to avail of that thing.

And then finally, my last comment really, about the sustainability of labs, you know, goes back to qualified human resources. You know, when you have a lab manager that gets maximum pay in Kosrae, in the FSM, $16,000 per annum, you know, trying to then recruit qualified people to take on those types of responsibilities in this very isolated community is really next to impossible.

So, where we've stepped in obviously is with funding from CDC. You know, we've been able to recruit some consultants, some very qualified consultants to come in and to work in the lab, you know, to help build the lab and insure that samples are being sent in on a timely basis or the results are understood and sent out to the physicians that, you know, et cetera, et cetera, and that good workers are kept, so that we can report back to CDC.

But you know, at the same time, when we are bringing in external consultants that are getting paid, you know, three or four times even that of their local counterparts, you know, it does create some issues. But this speaks to a larger sort of systemic chronic government level issue around pay scales and public service scales for technical staff that we can't really touch on at the moment.
And finally, the issue of procurement. So again you know, when we're talking about being able to procure sufficient lab supplies, or, you know, rapid test kits, and then supplies to either ship these things, you know, samples out to the reference laboratories. We're seeing extreme levels of stock cuts. We're seeing sort of inappropriate forecasting of needs because, again going back to the information around the data on patient size, you know, there's an inconsistency there.

There are no stockpiles locally for public health emergency responses. There are stockpiles for disaster emergency responses, but there are no stockpiles, currently at least from what I'm aware of, for public health emergencies.

So I wanted to just really - I'm sorry I've spoken a lot - but I just wanted to lay out sort of all of these different points.

Because when we're talking about sustainable timely and relative appropriate laboratory response for our island communities that do also impact the Continental United States because of the huge amount of travel among these populations to the Continental United States, I just really wanted to see if we can delve down really deep on some of these chronic critical issues that we've never really been able to address to the sufficient level that it needs to.

So, thank you for much for your time.

Eddie Ades: No. I should say, I'm really not qualified to answer to all of your points because they're very frustrating real issues in life that - I hear your pain. I wish I could resolve some of them. But you know, at the end of the day I think, you know, one message that I'll take home from this is that Hawaii's doing a great job.

Eddie Ades: And, you know, we - and the issue about Guam - people have been talking about that for a long time now. I know that there's been conversation. I'm not sure where that stands.

But you know, I am not necessarily the best person to carry this message forward. However, I will tell that if you are willing to put some of these points down into some sort of email, I would be happy to send that email forward to leadership here at CDC within the Emergency Operations Center in a way that would say, you know, some of the groups of islands that are feeling a little bit more pain.

And some of the issues are resolvable if you provided some funding. Some of them are never going to be easily resolvable but can be looked at, and maybe we can find other closer islands and/or regional labs, such as Guam, that would ease some of the pain.

So, I would just ask that you try to take these points that you've made to me so distinctly and very clear and send them to me in an email, and I'll try and take them forward. I think that the State Coordination Task Force has heard some of these before. I'm a different voice. I'm a different person.

I'm not sure I have any more influence than other people that are in the room or on the phone. But I promise you that I'll at least take it to/into the management leadership, so that they are very cognizant of the points that you've raised on the phone this afternoon.

That's the best I can do for you. Unfortunately, I can't solve a lot of the problems. I am happy and hopeful that at least what we are doing currently is
helpful. But we're not, obviously, to where we can solve all of you problems at this particular time.

I know that doesn't help you. But I promise if you put them out there for me, I will transfer them up the chain.

(Amy): Yes, I really appreciate that, Dr. Ades. I really do. And I think, as you said, these are things that have been repeated previously. And for us, it's really making sure that this remains on the table.

And it's not just specific to the lab. I think this is a chronic system across the board. But it is impacting labs, and so we do want to make sure that we do a very good job of providing good laboratory services for island communities.

And so some of these other issues, we just can't sort of let them lie low because they are so impactful in a negative way for effectiveness. So thank you so much for that. And I will send you - I do have some notes here in front of me - and so I will send that to you.

But also I'd like to reach out to other folks on the line, you know, from the Pacific. I hope that some of our lab consultants from our Zika response are on the line so they can probably ask more specific questions than I could, because I'm definitely not a lab person. But thank you. I really appreciate it.

Eddie Ades: And thank you for your comments. I do appreciate them. And I have also been known to raise several issues multiple times, because, you know, it's the squeaky wheel that sometimes gets paid attention to.

So we do need to continue to raise these points as often as people will allow. So keep doing it. It's important.
Jim Crockett:  Thanks, (Amy). We'll capture that. And again, this is a recorded session and we'll capture this part of the notes and it will be attached on the - a chance for others to listen to in a link here within 7-10 days if we are successful. That's our standard. So we capture that so others in the Pacific that may not have made the call or had the opportunity to be in this conversation also.

So Karen, can we see who else may be on the line with the consideration of time?

Coordinator: Yes, thank you. Our next question comes from Thane Hancock. Thane, a line is open.

Thane Hancock: Hi. Thank you everyone. This is Thane Hancock, I'm a Career Epidemiology Field Officer based in Guam. And I just want to thank (Amy) for sharing some of the issues that we face in the Pacific as far as getting testing samples to these small islands, and would like to echo just quickly her comments about needing additional certain lab support that Hawaii did a great job.

Guam with the Trioplex has also offered that testing to Chuuk and Palau, and it has been able to provide that as well. So, it's nice that Guam has sort of stepped into that regional role. But certainly there's a lot more support that can be done for that.

Two things I wanted to ask or bring up. One comment is, the Trioplex has been amazingly helpful for us in the Pacific. Knowing that our specimens are being run for Zika, dengue, and CHIK all at the same time has been really helpful for our sort of acute febrile illness surveillance.
And I think for us in the Pacific, as you know, new infectious diseases has become prominent in the region. And if more of these sort of panel tests, if, you know, feasible and costs willing, are developed there they're helpful.

And then the second part sort of in regards to the regional testing, one thing that we have benefitted from in the small islands is the GeneXpert, sort of. I've heard it called ‘PCR in a pouch testing’ that has been rolled out in some of the islands.

And so I know that - my understanding - that CDC is not, you know, really involved in developing these sort of technologies. But those are also helpful as a way of getting sort of testing capacity into the small islands that don't really have the ability to really appropriately run open platform PCR machines.

So that's sort of my two questions and comments. One is, I really appreciate the Trioplex. And two, is there movement toward sort of these ‘PCR in a pouch testing’ for Zika? Thank you.

Eddie Ades: Thank you for the question. I haven't heard anything about the using GeneXpert for Zika. I think the only thing that we're doing at the moment is that we've set up the individual assay for Zika as a single assay, so that you don't have to run all three at any one particular time. But beyond that I haven't heard that there has been any push go towards the GeneXpert.

And that's - you know - but I can ask other people. I think Dr. Lanciotti is on the phone and he might have some other information. But to my knowledge, no one's. That's a new question to me.

Robert Lanciotti: Yes, this is Rob. I actually am not familiar with the GeneXpert.
Thane Hancock: Okay, thanks. And again, I know it's a commercial entity. So, you're not sure about them what they're going to develop. But I just wanted to find out.

And just as far as that Trioplex testing, you know, we're able to identify cases of dengue and chikungunya, I mean, dengue in the islands were just originally thought to be Zika, but has tested positive via the Trioplex for dengue.

Eddie Ades: Okay, great. Thank you very much for your comments. And I'll ask around about the GeneXpert issue.

Jim Crockett: Thane, thanks for all your work out in the Pacific. It's really appreciated.

Karen, can I ask that for those that want to call in, could you remind us of the process for those that have a question to ask? We've had a couple show up on the chat line with that question.

Coordinator: Yes. Thank you. If you'd like to ask a question, once again, please press star, then 1- star then 1- and record your first and last name when prompted.

Jim Crockett: Thank you.

Coordinator: You're welcome. The next question comes from Francine Lang. Ma'am, your line is open.

Francine Lang: I'm calling from the Virgin Islands. We have some similar problems to the Pacific, so I just wanted to put a little support their way. The same problems they're talking about is the length of time to get samples processed and everything.

We experience that with chikungunya - sometimes three to six months to get results back. It was very, very disheartening.
We have worked hard with the clinicians for them to actually do the testing or, you know, prescribe the testing. And they weren't getting the results back. We had clients calling, patients calling, you know, very upset that they didn't know whether they were positive. But they knew that had chikungunya because of all the pains and everything they had.

When Zika happened, we were almost in the same boat. But then CDC opened the surge lab in Atlanta, which for us is a lot closer than Colorado. I know neither of them are close for the Pacific. But it really made a big difference. And Zika also made it possible for us to get some investment to try to develop our local public health lab.

So for that reason, I would say I would support any assistance you guys could provide in getting that regional lab in Guam that they would be able to have access to. I'm not a lab person either. I'm just the PHEP Program.

But I know that that was a major challenge for us - was getting the results in a timely manner and getting a lab up and running. Ours is still not up and running yet. Hopefully it will be later this year.

But those are like incremental steps of making the response much easier. We had situations where - our samples have to go off-island. We use FedEx and unfortunately, even though Puerto Rico is right next to us, when we had, during chikungunya, we would send our samples to the dengue lab in Puerto Rico which is 40 miles away.

FedEx flies to Memphis first before they take the samples back to Puerto Rico. And Memphis had a snow storm, or some kind of ice storm, or
whatever. And so the sample didn't get to Puerto Rico for three days, which of course, it could no longer be tested.

So, a lot of those things - the challenges that they have with how long it takes to get samples from point A to point B - they really resonate with me. So, if there's anything that we can do in the Virgin Islands to help support their request for a regional lab, I would like to say that, you know, we would be happy to. Thank you.

Eddie Ades: Appreciate the comments. And, yes, we're well familiar with the lab and the lab group down in USVI. And we are working - just so you're aware - our CLIA representatives here in Atlanta are working very closely with the USVI people, so that they can get their SOPs in place.

And once they get their SOPs in place, then they can start to run some tests and then eventually get CLIA certified, so that hopefully in the next few months, you actually will have testing on-island. That's our goal.

Francine Lang: Yes. And we appreciate that assistance. I look forward to the Pacific Islands being able to get to that point also. Thank you.

Eddie Ades: Yes. And I will do my best to convey that message up the chain. I promise.

Jim Crockett: Karen, if I can just a quick side note for Jill McCready. We do have you in the chat room. I understand you have connectivity issues.

If you can type in the question, we should be able to read it. And have it read in the room with us. So, Jill if you're hearing me, feel free to type away. We'll look at your question. So, Karen, back to you.
Coordinator: Yes, thank you. Are next question comes from Dana Thomas. Ma'am your line is open.

Dana Thomas: Hi. This is Dana and I'm in San Juan, Puerto Rico. I am a Career Epidemiology Field Officer also and colleague of Francine Lang's.

So, I wanted to ask - just - you mentioned what we do with our standard protocol now at the B-Cell lab with doing PCR first. And I just wanted to hear - you didn't really comment on that. But you said, you know, there's more discussion to follow, we are looking at new algorithms.

What is your opinion of that testing as a primary test?

Eddie Ades: You know - I - so this is Eddie. I'll let Dr. Lanciotti, maybe I'll let him answer first? And then I'll answer second? Let's see what Rob has to say first. He's the SME.

Jim Crockett: Stick him out in front there.

Eddie Ades: I'll stick him out. Let him put his neck on the chopping block first.

Robert Lanciotti: Well I don't think there's - you know. As long as what's negative by PCR is then sent for serology testing, I have no problem. We’ve actually done the testing simultaneously.

We've done IgM first and then PCR. We’ve done it the other way. It doesn't - you know - as long as there's no, you know, missing test.

I think the nice thing about doing PCR first is that you have an answer. It's a definitive answer. You don't have to worry about the serology. Especially in a
place like Puerto Rico, where there's going to be secondary flavivirus infections where the serology is not going to be helpful.

So, you know, again as long as you take the PCR-negatives and then do some serology, you'll still not resolve many of them. But I think it's a fine approach.

Eddie Ades: So I'll stand right behind Rob and say, I totally agree with his answer. Thank you, Rob, for going first.

Dana Thomas: Well, thank both. I mean, I know that we've previously done reflex testing with PCR. And I just, you know, if there was an alternate economic argument for one algorithm versus another?

Eddie Ades: So, I'll just answer that quickly. You know, originally when this response started, I think that there were very few labs that had the capability of doing the RT-PCR, and therefore the algorithm sort of was, you know, serology, et cetera, et cetera, et cetera.

Now that there are lots of labs that are capable of doing RT-PCR and the cost is obviously still spread out among the LRNs and whoever is receiving the Trioplex through us, it's a non-issue as far as I'm concerned.

And I'm very comfortable having the NAT testing or the RT-PCR done first. And again, there is multiple reasons for that but, as Rob indicated. If you get a positive it's done, and you don't have to go on to serology. So, I think that there's value there. So, I hope that answers your question.

Dana Thomas: It may even save money. No, it may even be more economical and it's certainly more thorough.
Robert Lanciotti: The other thing to consider, is that whether you're using the MAC-ELISA or even the InBios test, the throughput of PCR is much greater, you know, with the robotics and 96-well formats and so forth. You can process a lot more samples more easily than you can in serological tests.

Dana Thomas: And so, I think you know our protocol is that we do the InBios first and then we do confirmatory testing with MAC-ELISA?

Eddie Ades: Right.

Dana Thomas: So, well thank you. And thanks for all the excellent points. I appreciate it.

Eddie Ades: Absolutely. Thank you for the question. Here in Atlanta there is a question that was sent to us via text. And I'm going to read it.

It's from Jill McCready and it says "We often get negative PCR and IgM positive results. PRNT results show dengue titers greater than 80, but Zika great than 1280. Can we make any assumption that the Zika virus is the most likely cause of the recent infection and respond as appropriate? Most of these cases are nonpregnant women."

I'm going to ask Dr. Lanciotti to respond to that question.

Robert Lanciotti: So officially, the way we have decided to categorize cases is there has to be Zika neutralizing antibody and no detectable neutralizing antibody to any of the dengue serotypes. I think that's the most conservative way to go.
However, in the scenario you described where there's a large difference in neutralizing titer between Zika and one of the dengue viruses, I think it is likely that it's dengue.

However, we do have a list and I have it here that I continuously add to of situations where the dengue titer is significantly higher to Zika. And yet by PCR, it is actually, you know, Zika because of the original antigenic sin phenomenon.

I don't have a good handle on the percentage of time that happens. But if it happens often enough that, if we look at this disparity in titers and try to make some conclusions, we run into some problems. So, I think the way we're doing it now, where we see no detectable antibody to the dengue before we call it a Zika case, is the best way to go.

But I do agree that, in many cases when you see that large difference in titer, you could probably assume likely that it is dengue. But certainly not - there are certainly many cases where you could be misled by the serology. So…

Eddie Ades: Thanks, Rob.

Jim Crockett: Karen?

Eddie Ades: Go ahead.

Jim Crockett: No, I was going to say if there's a follow up to that question, please just go ahead and send it by type and we'll try and get that answered before this call ends. And at this point, I'll see if there are any other questions.
Coordinator: Yes, thank you. We do have a question coming from Chris Wayland. Sir, your line is open.

Chris Wayland: Aloha everyone. This is Chris Wayland of Hawaii State Labs. I just wanted to say how much we appreciated all the help that CDC Fort Collins and Atlanta has provided to us to get our testing to the level that we can support the Pacific in the manner that we have been able to. We certainly couldn't have done it without their help.

Some of the Amy's comments, I think, really resonate the importance of the ELC funding to Hawaii as well as to the Pacific Island jurisdictions. I think that needs to be well-documented. And some of the expansion of the ELC funding to incorporate cross-cutting and peer-to-peer lab visits, I think, is something that helps us here in the Pacific.

Also I want to put a plug in for the PIHOA Lab Revolving Fund. The transport is a real challenge out here, and Amy was very eloquent in the way that she described the costs and the frequency and the challenges associated with that.

I did want to ask a question about the consideration of including particularly American Samoa, and perhaps other jurisdictions in the Pacific, in a similar exemption to PRNT a confirmation because of the wide spread dengue that we've seen in some of the jurisdictions. Most of the PRNT is coming back undifferentiated flavivirus infections.

So, I think that this is resulting, you know, a lot of costly transport and some testing that's being done at Fort Collins that may not be very helpful and understanding the situation because of the cross reactivity. So, let me pause there and see if there's a response to that consideration.
Eddie Ades: So I had planned on making a comment about that. The answer is that we understand the issue that you all have with regard to cross-reactivity and dengue, et cetera, and so on, so forth. And we've seen some of the data that you've sent to us with regard to that.

We have absolutely no problem with the fact that you want to eliminate doing PRNT. The problem is that it's really not CDC's role to make that decision. We can guide you as to how you make application to eliminate it from the confirmatory testing.

The bottom line is that there's about four or five steps that are required from the FDA, in order for us to make application to them in order to get you all free from doing or continuing to do PRNT.

We went through those steps with Puerto Rico, and the FDA was very helpful in eliminating the need to do confirmatory testing for PRNT. So I believe with the data that you've sent to us, it's very clear that you've got a ton of cross-reactivity.

The issue is pretty clear. I think it's just a matter of having you all follow the four or five steps that are needed. And once we get that information, we can then send that forward to the FDA and ask - and appeal - to have the PRNT done away with in regard to testing out in the Pacific Islands and Hawaii area.

I hope that helps. And I sent that letter twice now out to different people, I believe - and you know - but haven't heard or seen anything back.
So if you are the right person to follow through on that, please feel free to send me an email and we'll forward that to you and see if we can get you what information you need, so that we can do this going forward.

Chris Wayland: Thank you.

Eddie Ades: We're happy to help you. It's just the question where, you know, our role is not to put that package together. It's just to guide you how to put that package together and then we will make the appeal in your stead. I hope that helps?

Chris Wayland: Yes. I'd like to see what the four or five steps are. Can you briefly describe them?

Eddie Ades: I honestly don't remember what they are off the top of my head. But we can - I - so if you'll just send me an email or send an email to Preparedness@CDC.gov, then we can get. I will directly send you a copy of the letter that Puerto Rico used to apply for that appeal.

Chris Wayland: Great. Thank you.

Eddie Ades: Yes, absolutely. Just send an email or you can send it directly to me. It's ewal@CDC.gov. And just send me an email, and I'll send you the cover letter that went to the FDA.

Chris Wayland: Okay. Sounds good. And just have one other comment for Thane, if you're still on the line. I think the GeneXpert technology may be of value in the Pacific for doing some more monitoring of antimicrobial resistance.

(Allen) was with us at the ELC HAI conference. And certainly for the detection of CARB CRE/CRPA that may be an expanded use to get some of
those microorganisms that have not only high levels of resistance, but high levels of transmissibility, identify those first and so you can initiate your containment activities to protect other patients in those areas.

So keep an eye out for some more on that, I think. Okay. I think that's all I have. Thanks.

Jim Crockett: We had a few technology problems inside the room here, but (Karen) if you're okay, we'd like to take more questions, if you're available and you will support this. For those on the call, I understand we were due to stop at the top of the hour here. But the presenters and the subject matter experts and the lab task force we have available, said they would be available for further questions.

So, if we can all support this, we're ready to receive the next question, if you have another.

Coordinator: At this time, I show no questions. But if you'd like to ask another question, please press star 1 and clearly record you name for question induction. One moment please, to see if we gather questions.

And I currently show no questions at this time.

Jim Crockett: That's real good. So it'll work out great. So you should have on your slides coming up the list of upcoming webinars we're expecting to have with the dates and the times associated with it.

Please share that with others as you see fit. In front of those, within three to five days prior, you should get an invitation coming out. We try to do a very wide distribution for those with the call and information. And again, share that information as you see fit. We'd appreciate further dissemination on that.
This information has been recorded. We'll do it attached to a link for those out in the Pacific and other places that might have missed the call, so that they'll have access to it. We'll kind of go from there.

So just for a reminder for today. If you have additional questions we didn't ask, or you weren't clear on the answer, or you'd like to readdress it at another angle, please send it to us at Preparedness@CDC.gov, again Preparedness@CDC.gov.

We will work the answer to the right place. That also applies to future webinars. If you have a question you'd like us to queue up before the actual webinar, whether it's communications, EPI surveillance, or other, please let us know.

With that in mind, I would like to say thank you for the call. Thank you for your time. Laboratory team, thanks for the second session with the Caribbean and Pacific focus. It's much appreciated. Thank you.

And we will close the call with that. Karen if you can stand online with us, thank you.

Coordinator: Please stand by all participants. Thank you for your participation. This concludes today's conference. You may now disconnect. Speakers, please stand by.

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